

### **REMARKS**

Applicant respectfully requests reconsideration.

Claims 1-21, 23, 28-33, 44, 46-58, 64-66, 71-74, 77-81, 84, 85, 89, 90, 95, 96, 98 and 99 are pending in this application. Claims 10-15, 29, 32, 45-57, 63-65, 70-73, 76-80, 83-84, 88-89, 94-95 and 97-98 are withdrawn (claim numbering is based on the corrected numbers). No claims are canceled.

Applicant has renumbered claims 17-99 to claims 16-98 to correct a typographical error in the previous claim numbering. The claims have also been amended to correct the dependencies. The claim numbering referred to in this amendment is based on the corrected claim numbers.

Claims 1, 7, and 22 have been amended. Support for the amendment to claims 1 and 22 is found in the specification at least on page 14, lines 1-3. Claim 7 has been amended to correct the dependency to claim 6. No new matter has been introduced.

As a result, claims 1-9, 16-20, 22, 27, 28, 30, 31, and 43 are pending for examination with claim 1 being an independent claim. No new matter has been added.

### **Election/Restrictions**

The Examiner has acknowledged Applicant's election of Group I (claims 1-21, 23, 28-33 and 44) with traverse filed March 7, 2006. The Examiner did not find the arguments regarding Groups I-III persuasive and has made the restriction requirement final.

The Examiner has acknowledged Applicant's request for rejoinder of Groups V, VI, VII and/or VIII upon the allowance of claim 1.

### **Objections to the Specification**

The Examiner objected to the specification as containing two contradictory descriptions of Figure 15A. The specification has been amended to correct a typographical error. The second recitation of "Figure 15A" has been corrected to "Figure 15B". Support for this amendment is found in Figure 15B which is labeled "with alum" as stated in the figure legend. No new matter has been introduced.

Accordingly, withdrawal of this objection is respectfully requested.

The Examiner objected to the specification because the numbering of the claims was incorrect. Applicant has amended the claim numbering to renumber claims 17-99 as claims 16-98. This was a typographical error and no new matter has been introduced. Applicant refers to the corrected numbering of the claims throughout this response.

Accordingly, withdrawal of this objection is respectfully requested.

#### Information Disclosure Statement

The Examiner has indicated that the Office is unable to locate a copy of the PTO-1449 form submitted with the IDS of March 21, 2005.

The IDS received by the USPTO on March 21, 2005 was not accompanied by a PTO-1449. The IDS refers to the International Preliminary Examination Report (IPER) for PCT/US03/21113 (Attorney Docket No. C1037.70041WO00). A copy of the IPER was included with the IDS. The references cited in the IPER were previously cited to the USPTO. These references were provided on PTO-1449 form submitted with an Information Disclosure Statement filed April 27, 2004.

The Examiner has further indicated that a complete translation of the reference listed as item B2 on the IDS filed April 29, 2004 was not provided and only the English version of the abstract has been considered. The U.S. published application (2004/0234960), which claims priority to reference B2, was cited in an IDS submitted December 5<sup>th</sup>, 2006. Applicant asserts that the Examiner's consideration of this US published application will satisfy consideration of reference B2.

#### Rejections under 35 U.S.C. §112

Claims 1-9, 16-20, 22, 17-28, 30, 31 and 43 are rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements.

Applicant believes the rejection under 35 U.S.C. §112, second paragraph, was intended for claims 27-28 and not 17-28 and have addressed the rejection on this assumption. Claim 1 has been amended to recite that the immunostimulatory nucleic acid molecule comprises an unmethylated CpG motif. Claim 22 has been amended to recite that the at least four CpG motifs

are unmethylated. Support for these amendments is found in the specification at least on page 14, lines 1-3. No new matter has been introduced.

Reconsideration and withdrawal of this rejection is respectfully requested.

Claim 7 is rejected under 35 U.S.C. §112, second paragraph, for lack of antecedent basis. Claim 7 has been amended to depend from claim 6 which provides antecedent basis for the recitation “nucleic acid vector”. No new matter has been introduced.

Reconsideration and withdrawal of this rejection is respectfully requested.

#### Rejections Under 35 U.S.C. §103

Claims 1-9, 16-20, 22, 17-28, 30, 31 and 43 are rejected under 35 U.S.C. §103(a) as being unpatentable over WO 01/022972 (Krieg *et al.*). According to the Examiner, Krieg *et al.* teaches a composition comprising an immunostimulatory nucleic acid with a sequence that differs from SEQ ID NO.:1 by the nucleic acid residue at position 20 (A in place of T). The Examiner further states that “Krieg *et al.* suggests the exchange of the adenine with thymine.” According to the Examiner, one of ordinary skill in the art would have been motivated to exchange adenine for thymine to enhance the immunostimulatory activity of the immunostimulatory nucleic acid.

Applicant respectfully disagrees. One of ordinary skill in the art would not be motivated to modify the sequence disclosed as SEQ ID NO.:888 to change the nucleic acid residue at position 20 to be thymine to produce the sequence of SEQ ID NO.:1 because there is no suggestion in Krieg *et al.* to make such a change to this nucleic acid. The immunostimulatory nucleic acid (SEQ ID NO.:320) which the Examiner has used as the basis for the motivation to make this change is a completely different nucleic acid than SEQ ID NO.:888. This specific immunostimulatory nucleic acid contains different structural features than both SEQ ID NO.:888 and SEQ ID NO.:1. Specifically, only two CpG motifs and not the at least four CpG motifs of SEQ ID NO.:888 or SEQ ID NO.:1 are present in this sequence, and SEQ ID NO.:320 contains a poly C tail rather than a poly T tail as in SEQ ID NO.:1 and SEQ ID NO.:888. There is no motivation for one of ordinary skill in the art to make a single nucleic acid substitution to one nucleic acid molecule based on the results of a structurally different nucleic acid sequence.

According to the Examiner, one of ordinary skill in the art would have had a reasonable expectation of success because Krieg *et al.* have demonstrated the enhancement of immunostimulatory activity.

Applicant respectfully disagrees. Although the substitution of a thymidine residue for an adenine residue in immunostimulatory nucleic acid SEQ ID NO.:320 resulted in slightly higher activity, there is no suggestion by Krieg *et al.* that a similar effect would occur if the same substitution was made in SEQ ID NO.:888. As discussed above, these immunostimulatory nucleic acids have completely different sequences. The remainder of the paragraph in Krieg cited by the Examiner describes other changes at different places in the molecule which have different effects and different degrees of effect. One of ordinary skill in the art would have no expectation of success that making a change that resulted in a slightly higher activity in SEQ ID NO.:320 would affect the immunostimulatory ability of SEQ ID NO.:888 in the same or similar positive way.

Reconsideration and withdrawal of this rejection is respectfully requested.

**CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



Marie A. Aucoin, Reg. No. 59,414  
WOLF, GREENFIELD & SACKS, P.C.  
Federal Reserve Plaza  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
(617) 646-8000

Date: March 21, 2007  
x03.22.07